ANALYTON™ LABS

AN-2026-00024

Issued 2026-10-28

Certificate of analysis

Issued by ANALYTON LABS, analytical testing laboratory, under ANALYTON GC 1.1.

BATCH ID AMENDED 2026-10-29
REPORT FIELD OMITTED 2026-10-29

Client	Molequa
Sample	Epithalon, lyophilised powder, vial labelled 10 mg
Batch number	MQ-EPITHALON-202609
Client lot reference	MQ-EPITHALON-202609, as declared by the client
Matrix	Research peptide

Supersedes	AN-2026-00006
Sample received	2026-09-08
Date of issue	2026-10-28
Determinations performed	20

SUMMARY OF RESULTS

DETERMINATION	METHOD	RESULT	SPECIFICATION
Appearance	Visual	**White to off-white powder**	White to off-white powder
Purity	RP-HPLC, C18, 214 nm, area %	**99.93 ± 0.20 % (k = 2)**	>= 98.0 %
Related substances	RP-HPLC, 214 nm; LOD 0.01 %, LOQ 0.03 %, reporting threshold 0.05 %	**Largest single impurity 0.07 % at RRT 0.96 (± 0.03 %); total impurities 0.07 %, i.e. 0.006 mg per vial**	Single <= 1.0 %, total <= 2.0 %
Impurity profile	RP-HPLC with LC-HRMS assignment	**RRT 0.96, 0.07 %, same mass (isoAsp)**	Peaks above 0.05 % reported (ICH Q3B)
Net peptide content	Assay	**84.14 ± 1.2 % w/w (k = 2)**	—
Fill weight	Gravimetric	**10.95 ± 0.05 mg**	Labelled 10 mg
Peptide per vial	Calculated from fill weight and net peptide content	**9.21 mg per vial labelled 10 mg, i.e. 92.1 % of label**	95 to 105 % of label
Vial-to-vial consistency	Gravimetric, two vials of the batch	**10.95 and 10.90 mg, difference 0.5 %**	<= 5 %
Counter-ion content	Ion chromatography, suppressed conductivity	**Acetate 9.50 % w/w (± 0.57 %), i.e. 1.04 mg per vial**	—
Trifluoroacetate	Ion chromatography, LOQ 20 ppm	**Not detected**	—

DETERMINATION	METHOD	RESULT	SPECIFICATION
Water content	Coulometric Karl Fischer, USP <921>	**5.80 ± 0.29 % w/w (k = 2), i.e. 0.64 mg per vial**	<= 8.0 %
Mass balance	Peptide + counter-ion + water	**84.14 + 9.50 + 5.80 = 99.44 % (± 1.3 %)**	Close to 100 %
pH	Potentiometric, 10 mg/ml in water	**5.2**	4.4 to 6.0
Solubility	Visual	**>= 100 mg/ml in water**	>= 60 mg/ml
Bacterial endotoxins	Kinetic chromogenic LAL, USP <85>	**< 0.05 EU/mg (< 0.55 EU per vial)**	<= 10 EU/mg
Sterility	Membrane filtration, USP <71>; fluid thioglycollate 30 to 35 °C and soya bean casein digest 20 to 25 °C	**No growth after 14 days, 2 vials**	No growth
Microbial enumeration	Plate method, USP <61> and <62>	**TAMC < 10 CFU/g, TYMC < 10 CFU/g; E. coli, Salmonella, S. aureus and P. aeruginosa absent in 1 g**	TAMC <= 1000 CFU/g, TYMC <= 100 CFU/g, specified organisms absent
Residual solvents	Headspace GC, USP <467>	**Acetonitrile 45 ppm; N,N-dimethylformamide, methanol, dichloromethane, diethyl ether, diisopropyl ether and piperidine each < 10 ppm (LOQ 10 ppm)**	ICH Q3C: acetonitrile <= 410, DMF <= 880, methanol <= 3000, dichloromethane <= 600, ethers <= 5000 ppm
Elemental impurities	ICP-MS after microwave digestion (HNO3/H2O2), USP <233>	**Cd, Pb, As, Hg < 0.05 µg/g; Co, V, Ni < 0.10 µg/g, all below LOQ**	ICH Q3D(R2) Class 1 and 2A, parenteral PDE
Chiral purity (D-amino acids)	Acid hydrolysis (6 M DCl in D2O, 110 °C, 24 h), Marfey's derivatisation (FDAA), LC-MS	**D-Asp 0.12 %, D-Glu 0.05 %, D-Ala < 0.05 %; Gly achiral; sum of D-forms 0.19 %**	Each D-amino acid <= 0.2 %, sum of D-forms <= 0.5 %
Compound screening	LC-HRMS full scan, m/z 100 to 2000, against library: fentanyl and analogues, DSIP, pinealon, protected intermediates (tBu, Boc, Trt, Pbf, Fmoc), free amino acids	**None detected above 0.05 % area**	No foreign compound above 0.05 % area

Labelled 10 mg / **9.21 mg peptide** / 92.1 % of label

Labelled 10 mg; the container held 10.95 mg of powder when weighed, of which 84.14 % w/w is peptide.



SIGNATURE

NAME	O. Noga
ROLE	Head Laboratory Technician
DATE	2026-10-28



The sample

Sample	Epithalon, lyophilised powder, vial labelled 10 mg
Batch number	MQ-EPITHALON-202609
Client lot reference	MQ-EPITHALON-202609, as declared by the client
Matrix	Research peptide
Received	2026-09-08

Chromatographic purity by reversed-phase HPLC

PRINCIPLE

The sample is separated on a C18 stationary phase under a water and acetonitrile gradient, both modified with trifluoroacetic acid, and the eluent is monitored by ultraviolet absorbance at 214 nanometres, where the peptide bond itself absorbs. Detection at 214 rather than 280 is deliberate: 280 sees only aromatic residues, so a peptide without tryptophan, tyrosine or phenylalanine is close to invisible at that wavelength.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Resolution between the main peak and its nearest neighbour	not less than 1.5	1.8 (main peak against RRT 0.96)
Tailing factor of the main peak	not more than 2.0	1.1
Theoretical plates	not fewer than 2000	30 100 (apparent, gradient)
Relative standard deviation of replicate injections	not more than 2.0 per cent	0.6 per cent, 6 injections

PURITY

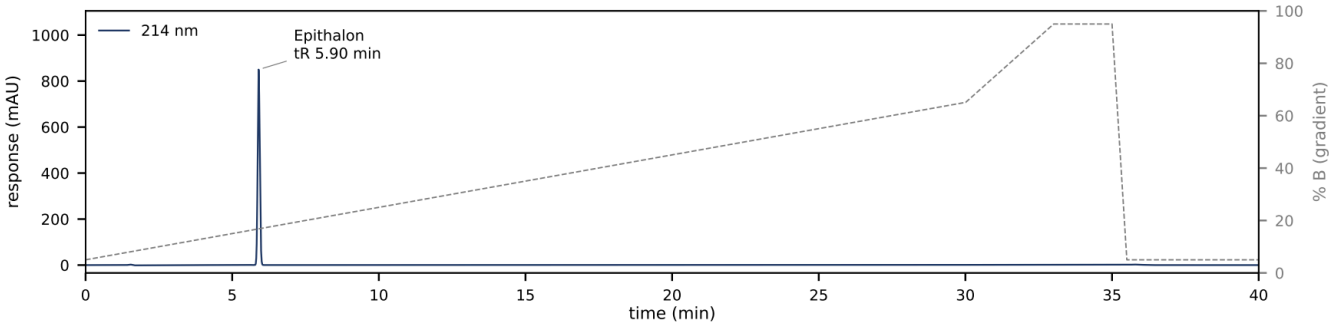
99.93 ± 0.20 % (k = 2)

Against >= 98.0 %

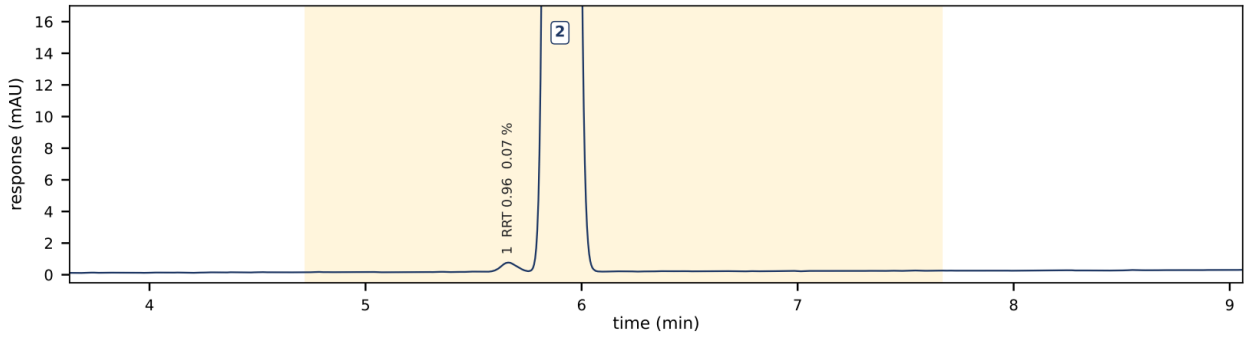
Epithalon 10 mg · RP-HPLC purity, 214 nm

Column C18, 4.6 × 150 mm, 3 µm, 40 °C; flow 1.0 ml/min; A: 0.05 % TFA in water; B: 0.05 % TFA in acetonitrile; gradient 5 to 65 % B in 30 min, 65 to 95 % B by 33 min, 95 % B to 35 min, return to 5 % B, equilibration to 40 min; injection 10 µl, 1.0 mg/ml in water (10 µg on column).

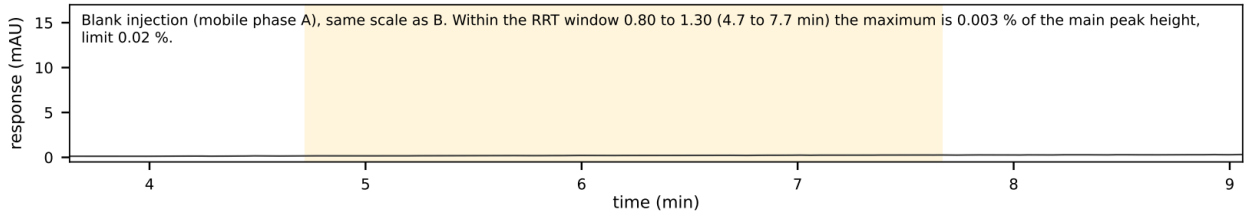
A. Full trace 0 to 40 min, full scale



B. Expanded view 0 to 2 % of the main peak height (17.0 mAU); main peak Epithalon tR 5.90 min off scale; impurities above the 0.05 % reporting threshold, numbered as in the table; yellow band = RRT window 0.80 to 1.30



C. Blank injection before the sequence



D. Peak table and system suitability

Peak	tR (min)	RRT	Area (%)	Height (mAU)	Mass shift	Assignment
1	5.66	0.96	0.07	0.60	same mass	Asp to isoAsp isomerisation (1× Asp in sequence)
2	5.90	1.00	99.93	850		Epithalon (main peak)

Purity (main peak area of all peaks): 99.93 % · total impurities 0.07 % · largest impurity 0.07 % at RRT 0.96

System suitability (USP <621>): resolution main peak / RRT 0.96 = 1.8 (≥ 1.5); tailing factor T = 1.1 (0.8 to 1.5); theoretical plates N = 30,100 (≥ 5,000, apparent in gradient elution, peak width at half height 0.08 min); S/N at 0.03 % = 13 (≥ 10); area RSD of 6 standard injections = 0.6 % (≤ 2.0 %).

Integration: reporting threshold 0.05 %, LOD 0.01 %, LOQ 0.03 %; noise 0.039 mAU peak to peak within ± 1 min of the main peak; baseline drift 1.5 mAU over the gradient; system peaks at t0 1.5 min and at the gradient return at 35.8 min are also present in the blank and are not integrated.

Wavelength 214 nm: the molecule has no aromatic residue and gives no signal at 280 nm; the peptide bond is the only usable absorption. Main peak 280/214 response ratio 0.000.

RP-HPLC CHROMATOGRAM AT 214 NM: FULL TRACE, EXPANDED VIEW, BLANK INJECTION AND PEAK TABLE

Water content

PRINCIPLE

Water in the sample reacts stoichiometrically with iodine generated coulometrically in the titration cell, and the charge passed gives the mass of water directly. The coulometric form is used rather than the volumetric because the quantities here are small.

SYSTEM SUITABILITY APPLIED

Cell blank drift	stable before the determination begins
Recovery of a water standard	97.5 to 102.5 per cent
Replicate agreement	within 0.2 per cent absolute

WATER CONTENT

5.80 ± 0.29 % w/w (k = 2), i.e. 0.64 mg per vial

Against <= 8.0 %

Bacterial endotoxins

PRINCIPLE

Lysate from the amoebocytes of the horseshoe crab is activated by bacterial endotoxin through a protease cascade, which cleaves a chromogenic substrate. The rate at which colour develops is proportional to endotoxin concentration, and the onset time is read against a standard curve prepared from control standard endotoxin.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Positive product control recovery	50 to 200 per cent	97 per cent

BACTERIAL ENDOTOXINS

< 0.05 EU/mg (< 0.55 EU per vial)

Against <= 10 EU/mg

Sterility

PRINCIPLE

The contents are transferred under aseptic conditions to fluid thioglycollate medium and to soya bean casein digest medium, and incubated for fourteen days at the temperatures each medium requires. Growth in either medium is a failure.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Incubation	not fewer than 14 days	14 days

STERILITY

No growth after 14 days, 2 vials

Against No growth

Microbial enumeration

PRINCIPLE

A prepared portion is plated onto soya bean casein digest agar for total aerobic microbial count and onto Sabouraud dextrose agar for total combined yeasts and moulds, and colonies are counted after incubation.

SYSTEM SUITABILITY APPLIED

Growth promotion of each medium	confirmed
Method suitability against the product	recovery within a factor of two
Negative control plates	no growth

MICROBIAL ENUMERATION

TAMC < 10 CFU/g, TYMC < 10 CFU/g; E. coli, Salmonella, S. aureus and P. aeruginosa absent in 1 g

Against TAMC <= 1000 CFU/g, TYMC <= 100 CFU/g, specified organisms absent

Residual solvents

PRINCIPLE

A weighed portion is equilibrated in a sealed vial and the vapour above the sample is sampled and separated by gas chromatography, with detection by mass spectrometry or flame ionisation. Sampling the headspace rather than the solution keeps involatile matrix out of the instrument.

SYSTEM SUITABILITY APPLIED

Resolution between the two closest eluting solvents	not less than 1.0
Signal to noise at the limit of quantitation	not less than 10 to 1
Repeatability of the standard	not more than 15 per cent relative standard deviation
System blank	no interfering peak at any target retention time

RESIDUAL SOLVENTS

Acetonitrile 45 ppm; N,N-dimethylformamide, methanol, dichloromethane, diethyl ether, diisopropyl ether and piperidine each < 10 ppm (LOQ 10 ppm)

Against ICH Q3C: acetonitrile <= 410, DMF <= 880, methanol <= 3000, dichloromethane <= 600, ethers <= 5000 ppm

Elemental impurities by ICP-MS

PRINCIPLE

The sample is digested in acid under microwave pressure and introduced into an argon plasma at approximately 7000 kelvin, which atomises and ionises the elements present. Ions are separated by mass to charge in a quadrupole and counted individually, which is what puts the technique at parts per billion.

SYSTEM SUITABILITY APPLIED

Internal standard recovery	80 to 120 per cent
Spike recovery in matrix	70 to 150 per cent
Calibration correlation coefficient	not less than 0.995
Digestion blank	below the reporting limit for every element
Drift check across the sequence	within 20 per cent

ELEMENTAL IMPURITIES

Cd, Pb, As, Hg < 0.05 µg/g; Co, V, Ni < 0.10 µg/g, all below LOQ

Against ICH Q3D(R2) Class 1 and 2A, parenteral PDE

Compound screening

PRINCIPLE

The sample is acquired in both positive and negative ionisation and the detected features are compared against reference standards held by the laboratory and against a spectral library, with confirmation by retention time and fragmentation where a standard is available.

SYSTEM SUITABILITY APPLIED

Reference standards injected in the same sequence	confirmed for every reported identification
Mass accuracy	within 5 ppm
Both polarities acquired	confirmed
Solvent blank between injections	no carryover above the reporting threshold

COMPOUND SCREENING

None detected above 0.05 % area

Against No foreign compound above 0.05 % area

Controls carried in the same sequence

Blank	Solvent blank (mobile phase A) injected before the sequence; no peak above 0.02 % of the main peak within RRT 0.80 to 1.30
Reference standard	In-house reference standard RS-EPI-01 (purity assigned against a primary standard, stored at -20 °C) injected at the start and end of the sequence; area difference 0.4 %, retention time within 0.1 min

Verify this certificate against the register

SCAN TO VERIFY

Scan the code, or open `https://analyton.com/verify/` and enter the report number with this key:

PCJ4MTCH67

The register returns every result on this report, the date of issue and the current status.

END OF REPORT